REMARKS

Applicant wishes to thank the Examiner for the acceptance of the CPA and for the examination of the pending claims. Claims 59 through 71 have been added by this amendment. Further, by this amendment, Claims 36 and 45-53 are cancelled. Therefore, Claims 35, 37-44, and 54-71 are presented for examination. No new matter has been added by this amendment.

Regarding the Restriction Requirement

The Examiner requested restriction of the Claims under 35 U.S.C. 121, to either:
Group II, Claims 35-44 and Claims 54-58, drawn to introducing the SP-D protein, or
Group III, Claims 45-53, drawn to introducing a vector expressing an SP-D protein.

Applicant hereby elects Group II, Claims 35-44 and Claims 54-58. Accordingly, Claims 45-53 have been cancelled without traverse, for being drawn to a non-elected invention. Applicant reserves the right to pursue these cancelled claims in a continuing application.

Discussion of Rejection Under 35 U.S.C. § 112

Claims 35-44 and 54-58 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

The Examiner requested that the term "SP-D" be replaced with the term "surfactant protein-D" in the independent Claims. Accordingly, this amendment has been made to Claims 35, 54, 55, 57, and 58.

The Examiner also rejected Claims 35-44 and 54-58, for the recitation of the term "substantially purified" in reference to SP-D. Claims 35, 54, and 55 have now been amended to remove the term "substantially purified" and to recite "consisting essentially of" rather than "comprising," as suggested by the Examiner. Further, the term "comprising" in Claims 57 and 58 has been replaced with "consisting essentially of." Thus, the newly amended phrase of Claims 35, 54, 55, 57, and 58 now reads "consisting essentially of mammalian surfactant protein-D (SP-D) protein" to improve the clarity of the claimed invention. Additionally, the limitation "wherein said composition is substantially free of phosphatidylcholine" has been deleted from Claims 54 and 55, as being redundant in light of the other claim amendments. Similarly, Claim 36, formerly depending from Claim 35, is being cancelled as being redundant in light of the

amendments to Claim 35. Claim 37, formerly depending from Claim 36, has now been amended to be dependent from Claim 35.

The Examiner provided an additional suggestion for overcoming the rejections on page 5 of the Office Action. Accordingly, new claims 59 through 71, containing the language "administering a recombinantly expressed mammalian surfactant protein-D (SP-D) protein" have now been added to address the Examiner's second suggestion.

The amendments discussed herein were made to advance prosecution of the claims, and do not indicate Applicant's agreement with the merits of the rejection. Applicant reserves the right to pursue claims of broader scope in further prosecution.

Applicant has attempted to address all of the Examiner's concerns regarding the alleged indefiniteness of the claims. Therefore, Applicant respectfully requests withdrawal of all rejections under 35 U.S.C. § 112.

Discussion of Rejection Under 35 U.S.C. § 102

The Examiner has rejected Claims 35-39, 54, and 58 under 35 U.S.C. § 102(e) as being anticipated by Cochrane et al. (U.S. Patent No. 6,013,619).

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. ...There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991).

Claims 35, 54, and 58, as now amended from "comprising" to "consisting essentially of," are not anticipated by Cochrane because Cochrane does not teach every element of the claimed invention. The Cochrane reference discusses surfactant proteins derived from natural sources that can be used as a part of a surfactant composition. However, Cochrane does not teach or suggest using any of the pulmonary SP proteins by themselves. Instead, they are used as a part of the surfactant composition which also typically includes some sort of lipid. In the Cochrane reference, all of the examples which include the presence of proteins also include a lipid or phospholipid.

It does not appear that Cochrane contemplated the use of surfactant proteins without the concomitant presence of some type of lipid molecule. For example, Cochrane states that the surfactant composition contains a "surfactant molecule" admixed with liposomes or phospholipids:

> *"The surfactant composition is prepared by admixing a solution of a surfactant molecule with a suspension of liposomes, or by admixing the surfactant molecule with a suspension of liposomes, or by admixing the surfactant molecule and phospholipids directly in the presence of organic solvent"* (Col 12, lines 3-8).

Cochrane teaches how the presence of the protein improves the surfactant ability of the lipid which is present in the composition:

> *"A preferred synthetic pulmonary surfactant comprises one or more phospholipids and a protein or polypeptide, in which the polypeptide, when admixed with a phospholipid, forms a synthetic pulmonary surfactant having a surfactant activity greater than the surfactant activity of the phospholipids alone"* (Col 5, lines 60-65).

Cochrane also suggests ranges of the ratio of protein to phospholipid to be used:

> *"A synthetic pulmonary surfactant used in the present invention typically contains a polypeptide:phospholipid weight ratio in the range of about 1:7 to about 1:1,000"* (Col 6, lines 32-34).

Cochrane does not suggest the use of any natural surfactant protein without being in admixture with some sort of lipid molecule – such as a phospholipid or liposome moiety. Therefore, one of skill in the art, upon reading the Cochrane reference, would not come to the conclusion that a composition "consisting essentially of surfactant protein-D (SP-D) protein" would be useful as a treatment for pulmonary disease.

Because the cited reference does not teach each and every element of the claimed invention, Applicant asserts that Claims 35-39, 54, and 58, as now amended, are not anticipated

by the Cochrane reference. For all of the above reasons, Applicant respectfully requests withdrawal of the rejections of Claims 35-39, 54, and 58 under 35 U.S.C. § 102(e), and allowance of the pending application.

Conclusion

Applicant has endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If any issues remain that may be addressed by a phone conversation, the Examiner is invited to contact the undersigned at the phone number listed below. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: August 28, 2003

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AMENDMENTS TO THE CLAIMS

Claims 1-34 (Cancelled)

35. (Currently amended) A method for the prevention and treatment of pulmonary disease comprising: introducing a composition ~~comprising~~ consisting essentially of ~~substantially purified~~ mammalian surfactant protein-D (SP-D) protein into a human in an amount effective to reduce the symptoms of, or prevent, pulmonary disease.

36. (Cancelled)

37. (Previously added) The method of Claim ~~36~~ 35 wherein the pulmonary disease is selected from the group consisting of: emphysema, bacterial infections, viral infections, and fungal infections.

38. (Previously added) The method of Claim 37 wherein said SP-D protein is administered intratracheally.

39. (Previously added) The method of Claim 38 wherein said SP-D protein is introduced by aerosolization.

40. (Previously added) The method of Claim 39 wherein said method further comprises administration of IL-4.

41. (Previously added) The method of Claim 39 wherein said method further comprises administration of SP-A.

42. (Previously added) The method of Claim 39 wherein said method further comprises administration of SP-B.

43. (Previously added) The method of Claim 39 wherein said method further comprises administration of SP-C.

44. (Previously added) The method of Claim 39 wherein said method further comprises administration of IL-4, SP-A, SP-B, and SP-C.

Claims 45 through 53: (Cancelled)

54. (Currently amended) A method for decreasing levels of phosphatidylcholine in the mammalian lung, comprising:

administering a composition ~~comprising~~ consisting essentially of ~~substantially purified~~ mammalian surfactant protein-D (SP-D) protein into a human in an amount effective to reduce said pulmonary phosphatidylcholine levels~~;~~

~~wherein said composition is substantially free of phosphatidylcholine~~.

55. (Currently amended) A method for the prevention and treatment of a viral disease comprising:

introducing a composition ~~comprising~~ consisting essentially of ~~substantially purified~~ mammalian surfactant protein-D (SP-D) protein into a human in an amount effective to reduce the number of viruses or symptoms of the viral disease~~;~~

~~wherein said composition is substantially free of phosphatidylcholine~~.

56. (Previously added) The method of Claim 55 wherein the viral disease is caused by a virus selected from the group consisting of: Adenovirus, RSV, and Influenza virus.

57. (Currently amended) A method for decreasing pulmonary virus titer, comprising:

introducing a composition ~~comprising~~ consisting essentially of a mammalian surfactant protein-D (SP-D) protein into a human in an amount effective to reduce said pulmonary virus titer.

58. (Currently amended) A method of inhibition of metalloproteinase activity and reactive oxygen species in the lungs, comprising:

administering a composition consisting essentially of surfactant protein-D (SP-D) protein to the lungs in an amount effective to inhibit metalloproteinase activity and reactive oxygen species.

59. (New) A method for the prevention and treatment of pulmonary disease comprising: administering a recombinantly expressed mammalian surfactant protein-D (SP-D) protein into a human in an amount effective to reduce the symptoms of, or prevent, pulmonary disease.

60. (New) The method of Claim 59 wherein the pulmonary disease is selected from the group consisting of: emphysema, bacterial infections, viral infections, and fungal infections.

61. (New) The method of Claim 60 wherein said recombinantly expressed mammalian surfactant protein-D (SP-D) protein is administered intratracheally.

62. (New) The method of Claim 61 wherein said recombinantly expressed mammalian surfactant protein-D (SP-D) protein is introduced by aerosolization.

63. (New) The method of Claim 62 wherein said method further comprises administration of IL-4.

64. (New) The method of Claim 62 wherein said method further comprises administration of SP-A.

65. (New) The method of Claim 62 wherein said method further comprises administration of SP-B.

66. (New) The method of Claim 62 wherein said method further comprises administration of SP-C.

67. (New) The method of Claim 62 wherein said method further comprises administration of IL-4, SP-A, SP-B, and SP-C.

68. (New) A method for decreasing levels of phosphatidylcholine in the mammalian lung, comprising:

administering a recombinantly expressed mammalian surfactant protein-D (SP-D) protein into a human in an amount effective to reduce said pulmonary phosphatidylcholine levels.

69. (New) A method for the prevention and treatment of a viral disease comprising:

administering a recombinantly expressed mammalian surfactant protein-D (SP-D) protein into a human in an amount effective to reduce the number of viruses or symptoms of the viral disease.

70. (New) A method for decreasing pulmonary virus titer, comprising:

administering a recombinantly expressed mammalian surfactant protein-D (SP-D) protein into a human in an amount effective to reduce said pulmonary virus titer.

71. (New) A method of inhibition of metalloproteinase activity and reactive oxygen species in the lungs, comprising:

administering a recombinantly expressed mammalian surfactant protein-D (SP-D) protein to the lungs in an amount effective to inhibit metalloproteinase activity and reactive oxygen species.